



## PATENT COOPERATION TREATY

PCT

11 MAY 2005

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY  
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 100896-1 WO	<b>FOR FURTHER ACTION</b> See Form PCT/PEA/416	
International application No. PCT/SE 03/01760	International filing date (day/month/year) 13.11.2003	Priority date (day/month/year) 15.11.2002
International Patent Classification (IPC) or national classification and IPC A61K31/575		
Applicant ASTRAZENECA AB		
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 5 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> sent to the applicant and to the International Bureau a total of sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>		
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the opinion</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>		
Date of submission of the demand  25.05.2004	Date of completion of this report  10.05.2005	
Name and mailing address of the international preliminary examining authority:   European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer  Cattell, James  Telephone No. +49 89 2399-8468 	

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International application No.  
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**Box No. I Basis of the report**

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1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
  - ☐ publication of the international application (under Rule 12.4)
  - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements\*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):*

**Description, Pages**

1-6 as originally filed

**Claims, Numbers**

1-14 as originally filed

- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages
  - ☐ the claims, Nos.
  - ☐ the drawings, sheets/figs
  - ☐ the sequence listing (*specify*):
  - ☐ any table(s) related to sequence listing (*specify*):
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages
  - ☐ the claims, Nos.
  - ☐ the drawings, sheets/figs
  - ☐ the sequence listing (*specify*):
  - ☐ any table(s) related to sequence listing (*specify*):

\* If item 4 applies, some or all of these sheets may be marked "superseded."

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**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

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**1. Statement**

Novelty (N)	Yes: Claims	7,10,11,12
	No: Claims	12,3,4,5,6,8,9,13,14
Inventive step (IS)	Yes: Claims	
	No: Claims	1-14
Industrial applicability (IA)	Yes: Claims	1-14
	No: Claims	

**2. Citations and explanations (Rule 70.7):**

**see separate sheet**

V.

- 1). The documents cited in the search report are to be regarded as being numbered D1-D6 in their order of citation. The IPEA intend to refer to the sections of these documents highlighted in the search report, unless otherwise specified.
- 2). Claim 1 refers to the addition of two ingredients one after the other into a container. This would seem very similar to putting milk in one's coffee, a process which does not result in any adhesion and hence falls within the scope of claim 1 under Article 33(2) PCT. Putting water into one's whisky falls within the scope of claim 3.
- 3). D1, D3-D4 describe the mixture of two ingredients which are then filled into a container. the propellant is then added. The propellant may be regarded as a "component" of claim 2, which is therefore not novel under Article 33(2) PCT.

Furthermore a product is not characterised by its manufacture. D1, D3 and D4 also therefore fall within the scope of claims 9 and 10.

- 4). D2, example 1, page 8 line 7, states that the formoterol and budesonide were weighed into a can which was then filled with tetrafluoroethane and crimped. It is clear that the "can" then becomes the final metered dose inhaler, i.e. the final container.

The process of "weighing" each active substance into the final container must have taken place in a stepwise manner.

Hence D2 falls within the scope of claims 1,2 ,4, 5, 6, 8, 9, 13, and 14 under Article 33(2) PCT.

- 5). The features of claims 7 and 10 to 12 would appear to be obvious selections of known ingredients.
- 6). The example given in the present application shows that te addition of budesonide followed by formoterol results in less adhesion. This could not have been predicted from the prior art under Article 33 PCT, but does not appear to have been clearly

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expressed in any of the claims.

- 7). For the assessment of the present claims 13-14 on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.